

**FIRST**  
**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

|                      |                   |
|----------------------|-------------------|
| Application Number   | 10/551,094        |
| Filing Date          |                   |
| First Named Inventor | Nicholas S. Bodor |
| Examiner Name        |                   |
| Attorney Docket No.  | 1033935-000020    |

**U.S. PATENT DOCUMENTS**

| Examiner Initials | Document Number | Kind Code (if known) | Name of Patentee or Applicant of Cited Document | Issue/Publication Date (MM-DD-YYYY) |
|-------------------|-----------------|----------------------|-------------------------------------------------|-------------------------------------|
|                   | 4,383,992       |                      | Lipari                                          | 05-17-1983                          |
|                   | 6,239,118       | B1                   | Schatz et al.                                   | 05-29-2001                          |
|                   | 5,424,296       |                      | Saven et al.                                    | 06-13-1995                          |
|                   | 5,510,336       |                      | Saven et al.                                    | 04-23-1996                          |
|                   | 5,506,214       |                      | Beutler                                         | 04-09-1996                          |
|                   | 4,659,696       |                      | Hirai et al.                                    | 04-21-1987                          |
|                   | 3,459,731       |                      | Gramera et al.                                  | 08-05-1969                          |
|                   | 4,478,995       |                      | Shinoda et al.                                  | 10-23-1984                          |
|                   | 5,310,732       |                      | Carson et al.                                   | 05-10-1994                          |
|                   | 5,401,724       |                      | Beutler                                         | 03-28-1995                          |
|                   | 5,106,837       |                      | Carson et al.                                   | 04-21-1992                          |
|                   | 4,497,803       |                      | Harada et al.                                   | 02-05-1985                          |
|                   | 6,194,395       | B1                   | Schultz et al.                                  | 02-27-2001                          |
|                   | 6,407,079       | B1                   | Müller et al.                                   | 06-18-2002                          |
|                   | 4,870,060       |                      | Müller                                          | 09-26-1989                          |
|                   | 4,727,064       |                      | Pitha                                           | 02-23-1988                          |
|                   | 4,596,795       |                      | Pitha                                           | 06-24-1986                          |
|                   | 4,764,604       |                      | Müller                                          | 08-16-1988                          |
|                   | 4,226,848       |                      | Nagai et al.                                    | 10-07-1980                          |
|                   | 4,250,163       |                      | Nagai et al.                                    | 02-10-1981                          |
|                   | 4,535,152       |                      | Szejtli et al.                                  | 08-13-1985                          |
|                   | 5,401,724       |                      | Beutler                                         | 03-28-1995                          |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Document Number | Kind Code (if known) | Country | Date of Publication (MM-DD-YYYY) | STATUS      |                     |                    |               |      |          |               |
|-------------------|-----------------|----------------------|---------|----------------------------------|-------------|---------------------|--------------------|---------------|------|----------|---------------|
|                   |                 |                      |         |                                  | Translation | Partial Translation | Eng. Lang. Summary | Search Report | IPER | Abstract | Cited in Spec |
|                   | 0 197 571       | A2                   | EP      | 10-15-1986                       |             |                     |                    |               |      |          | X             |
|                   | 90/12035        | A1                   | WO      | 10-18-1990                       |             |                     |                    |               |      |          | X             |
|                   | 31 18 218       | A1                   | DE      | 04-22-1982                       |             |                     |                    |               |      | X        | X             |
|                   | 33 17 064       | A1                   | DE      | 11-15-1984                       |             |                     |                    |               |      | X        | X             |
|                   | 2 189 245       | A                    | UK      | 10-21-1987                       |             |                     |                    |               |      |          | X             |
|                   | 0 149 197       | B1                   | EP      | 07-24-1985                       | X           |                     |                    |               |      |          | X             |
|                   | 0 094 157       | A1                   | EP      | 11-16-1983                       |             |                     |                    |               |      |          | X             |

**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials  | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                    | Tarasiuk et al., "Stability of 2-Chloro-2'-Deoxyadenosine at Various pH and Temperature", Archivum Immunologiae et Therapiae Experimentalis, Vol. 42, pp. 13-15, 1994, published by Birkhauser Publishers Ltd., Basel, Switzerland                              |
| Examiner Signature | Date Considered                                                                                                                                                                                                                                                 |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.W.S

**FIRST**  
**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2

|                      |                   |
|----------------------|-------------------|
| Application Number   | 10/551,094        |
| Filing Date          |                   |
| First Named Inventor | Nicholas S. Bodor |
| Examiner Name        |                   |
| Attorney Docket No.  | 1033935-000020    |

**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.                                                                                          |
|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                   | Romine et al., "A Double-Blind, Placebo-Controlled, Randomized Trial of Cladribine in Relapsing-Remitting Multiple Sclerosis", Proceedings of the Association of American Physicians, Vol. 111, No. 1, pp. 35-44, 1999, published by Blackwell Publishing, Malden, MA                                                                                    |
|                   | Tortorella et al., Current Opinion on Investigational Drugs, 2(12), pp. 1751-1756, 2001, published by PharmaPress Ltd., London, GB                                                                                                                                                                                                                       |
|                   | Selby et al., "Safety and Tolerability of Subcutaneous Cladribine Therapy in Progressive Multiple Sclerosis", Can. J. Neurol Sci., Vol. 25, pp. 295-299, 1998, published by Canadian Journal of Neurological Science, Calgary, Canada                                                                                                                    |
|                   | Rice et al., "Cladribine and progressive MS Clinical and MRI outcomes of a multicenter controlled trial", Neurology, Vol. 54, pp. 1145-1155, 2000, published by Lippincott Williams and Wilkins, Hagerstown, MD                                                                                                                                          |
|                   | Liliemark et al., "On the Bioavailability of Oral and Subcutaneous 2-Chloro-2'-Deoxyadenosine in Humans: Alternative Routes of Administration", Journal of Clinical Oncology, Vol. 10, No. 10, pp. 1514-1518, 1992, published by American Society of Clinical Oncology, Alexandria, VA                                                                   |
|                   | Karlsson et al., "Oral cladribine for B-cell chronic lymphocytic leukaemia: report of a phase II trial with a 3-d, 3-weekly schedule in untreated and pretreated patients, and a long-term follow-up of 126 previously untreated patients", British Journal of Haematology, Vol. 116, pp. 538-548, 2002, published by Blackwell Science Ltd., Oxford, UK |
|                   | Liliemark, "The Clinical Pharmacokinetics of Cladribine" Clin. Pharmacokinet, Vol. 32 (2), pp. 120-131, 1997, published by Adis International Limited, Wolters Kluwer Health, Yardley, PA                                                                                                                                                                |
|                   | Nogradi, "Dimethyl-β-Cyclodextrin", Drugs of the Future, Vol. 9, No. 8, pp. 577-578, 1984, published by JR Prous SA Publishers, Barcelona, Spain                                                                                                                                                                                                         |
|                   | Nakai et al., "Effects of Grinding on the Physical and Chemical Properties of Crystalline Medicinals with Microcrystalline Cellulose V: Comparison with Tri-O-methyl-β-cyclodextrin Ground Mixtures", Chem. Pharm. Bulletin, Vol. 28(5), pp. 1552-1558, 1980, published by Pharmaceutical Society of Japan, Tokyo, Japan                                 |
|                   | Saenger, "Clyclodextrin Inclusion Compounds in Research and Industry", Angew. Chem. Int. Ed. Engl., Vol. 19, pp. 344-362, 1980, published by Verlag Chemie, GmbH, Weinheim, Germany                                                                                                                                                                      |

Examiner Signature

/Nathan Schlientz/

Date Considered

03/16/2010

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.W.S